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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/531,889	06/05/2006	Achim Feurer	Le A 36 411	5900
35969	7590	07/07/2009		
Barbara A. Shimci Director, Patents & Licensing Bayer HealthCare LLC - Pharmaceuticals 555 White Plains Road, Third Floor Tarrytown, NY 10591			EXAMINER MURRAY, JEFFREY H	
			ART UNIT 1624	PAPER NUMBER
			MAIL DATE 07/07/2009	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/531,889

Applicant(s)

FEURER ET AL.

Examiner

JEFFREY H. MURRAY

Art Unit

1624

Period for Reply -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 April 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-4, 9, 10 and 12 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1-4, 10 and 12 is/are allowed.
- 6) ☒ Claim(s) 9 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-8508)
- 4) ☐ Interview Summary (PTO-413)
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____
- Paper No(s)/Mail Date _____

DETAILED ACTION

Status of Claims

1. Claims 1-4, 9, 10 and 12 are pending in this application. Claims 5-8 and 11 have been cancelled. This action is in response to the applicants' amendment after a non-final and reply filed on April 3, 2009.

Withdrawn Rejections/Objections

2. Applicant is notified that any outstanding rejection/objection that is not expressly maintained in this office action has been withdrawn or rendered moot in view of applicant's amendments and/or remarks.

Claim Rejections - 35 USC § 112, 1st paragraph

3. Claim 9 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a composition or a pharmaceutically acceptable salt thereof, does not reasonably provide enablement for any other compositions combined with "a further active compound" not previously described. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims.

4. The test of enablement is whether one skilled in the art could make and use the claimed invention from the disclosures in the application coupled with information known in the art without undue experimentation. (*United States v. Teletronics Inc.*, 8 USPQ2d 1217 (Fed. Cir. 1988)). Whether undue experimentation is needed is not based on a single factor, but rather a conclusion reached by weighing many factors (See *Ex parte*

Forman 230 USPQ 546 (Bd. Pat. App. & Inter. 1986) and *In re Wands*, 8 USPQ2d 1400 (Fed. Cir. 1988).

1) *Amount of guidance provided by Applicant.* While the Applicant has demonstrated within the application how to make pyrazolopyrimidines, applicant has provided no guidance, or provided any chemical or biological data and/or testing results of these particular compositions in combination with "a further active compound" or a pharmaceutically acceptable salt thereof.

The quantity of experimentation needed to make or use the invention must be considered to determine if undue experimentation is present. Here applicants do not describe in any explicit detail what types of further active compounds have been combined with the compositions. As currently written, these "medicament active ingredients" could cover a plethora of various disciplines as the "medicament active ingredients" term is undefined.

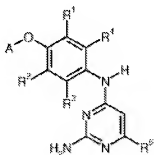
2) *Unpredictability in the art.* It is well established that "the scope of enablement varies inversely with the degree of unpredictability of the factors involved", and physiological activity is generally considered to be an unpredictable factor. (USPQ 18, 24 (CCPA 1970). See *In re Fisher*, 427 F.2d 833, 839, 166.

Applicants have provided no biological testing of any results where the compositions were combined with this "further active compound." Without this, one cannot simply infer that the results of the combination would be additive from the compositions or the active compounds alone. In many instances, the systematic screening of combinations of small molecules can reveal unexpected interactions

between the pathways on which they act. (Borisy, et. al., Proceedings of the National Academy of Sciences of the United States of America, 100(13) 7977-7982.)

3) *Number of working examples.* The compound core depicted with specific substituents represent a narrow subgenus for which applicant has provided sufficient guidance to make and use; however, this disclosure is not sufficient to allow extrapolation of the limited examples of compounds to enable the scope of the compositions combined with additional medicament active ingredients. Applicant has provided no working examples of any compositions which have been combined with additional medicament active ingredients in the present application.

4) *Scope of the claims.* The scope of the claims involves all of the millions of compositions of the following formula:



whereby the compound above is combined with "a further active compound" thus the scope of the claims is broad.

5) *Nature of the invention.* The invention relates to heteroaryloxy-substituted phenylaminopyrimidines, to a process for their preparation and to their use for preparing medicaments for the treatment and/or prophylaxis of diseases in humans and animals, in particular cardiovascular disorders.

6) *Level of skill in the art.* The artisan using Applicants invention would be a doctor with a M.D. degree, and having several years of professional experience.

MPEP §2164.01 (a) states, "A conclusion of lack of enablement means that, based on the evidence regarding each of the above factors, the specification, at the time the application was filed, would not have taught one skilled in the art how to make and/or use the full scope of the claimed invention without undue experimentation. *In re Wright*, 999 F.2d 1557,1562, 27 USPQ2d 1510, 1513 (Fed. Cir. 1993)." That conclusion is clearly justified here that Applicant is not enabled for treating the disease mentioned.

Claim Rejections - 35 USC § 112, 2nd paragraph

5. Claim 9 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 9 recites the limitation "a further active compound" in the last line of the claim. There is insufficient antecedent basis for this limitation in the claim. There is no definition of what is meant by a "further active compound" in particular what receptor the "further active compound" is deemed active for, or whether the compound is active "for" or "against" a receptor. No new matter permitted. Appropriate correction required.

Allowable Subject Matter

6. Claims 1-4, 10 and 12 are allowed.

7. Claims 1-4, 10, and 12 are free of the prior art. The closest prior art to these claims is Gour, et. al., WO 2001053331, which teaches a compound of claim 1 but for

the A variable. The prior art teaches the A variable as a phenyl ring, but not a 9-membered bicyclic heterocyclic ring as in the current application.

Conclusion

8. Claim 9 is rejected.
9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey H. Murray whose telephone number is 571-272-9023. The examiner can normally be reached on Mon.-Thurs. 7:30-6pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisors, Mr. James O. Wilson can be reached at 571-272-0661. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Jeffrey H Murray/
Patent Examiner , Art Unit 1624

/James O. Wilson/
Supervisory Patent Examiner, Art Unit 1624

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